In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-0904V UNPUBLISHED

RUSSELL RAMSEY,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES.

Respondent.

Chief Special Master Corcoran

Filed: October 12, 2022

Special Processing Unit (SPU); Dismissal; Insufficient Evidence; Tetanus, Diphtheria, acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leigh Finfer, Muller Brazil, Dresher, LLP, PA, for Petitioner.

James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On July 24, 2020, Russell Ramsey filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, $et\ seq.^2$ (the "Vaccine Act"). Petitioner alleges that he suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, due to the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine he received on March 10, 2019. Petition at 1, $\P\P$ 2, 10.

The record as it currently stands does not support Petitioner's claims. Specifically, there is evidence supporting a credible alternative cause which would explain Petitioner's shoulder pain. And the facts and circumstances surrounding Petitioner's left shoulder

¹ Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all Section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

injury are further complicated by the existence of a significant *prior* left shoulder injury and surgery. Thus, because Petitioner has failed to provide preponderant evidence to support his claim (whether styled as a Table or causation-in-fact claim), and/or to rebut this other, contrary evidence, I hereby DENY entitlement.

I. Relevant Procedural History

Along with the Petition, Mr. Ramsey filed his affidavit and some of the medical records required under the Vaccine Act. Exhibits 1-3, 5-9, ECF No. 1; Section 11(c). Several weeks later, he filed additional medical records. Exhibits 10-14, ECF No. 9; Exhibit 4, filed by CD on Aug. 11, 2020, without an accompanying Notice of Filing. On August 21, 2020, the case was activated and assigned to the Special Processing Unit. ECF No. 10.

On February 10, 2021, Respondent filed a status report identifying outstanding medical records and deficiencies in Petitioner's claim. ECF No. 15. Specifically, he reported that he had not received a copy of Petitioner's workers' compensation records filed by CD as Exhibit 4, noted that the medical records filed as Exhibit 13 appear to be for another individual, and requested updated medical records from Petitioner's July 2020 surgery and physical therapy ("PT"). *Id.* at 1. Regarding any factual issues which needed further development, Respondent stressed that the vaccine record did not indicate the site of vaccination, and that there existed evidence supporting the proposition that Petitioner's left shoulder pain was due to a workplace injury. *Id.* at 2. In response, Petitioner filed the requested updated medical records, a copy of Exhibit 4 which previously had been filed by CD, another affidavit, and a photograph of a tattoo on his left shoulder which he claims the vaccine administrator was attempting to avoid when administering the Tdap vaccine. Exhibits 4, 15-18, ECF Nos. 17-18.

On November 22, 2021, Respondent filed his Rule 4(c) Report, setting forth his specific objections to compensation in this case. ECF No. 24. He argued that a Table SIRVA could not succeed "because there is another abnormality or condition that can explain [P]etitioner's condition." *Id.* at 13; see 42 C.F.R. § 100.3(c)(10)(iv) (2017) (fourth criterion listed in the Qualifications and Aids to Interpretation ("QAI") for SIRVA). Respondent noted evidence of Petitioner's prior condition - including former injuries and degenerative changes, and the previously-mentioned workplace accident on March 10, 2019 – referenced the same day as the date of vaccination. *Id.* at 13-14.

On July 6, 2022, I issued an Order to Show Cause, allowing Petitioner a final chance to obtain and to file the evidence needed to support his allegations. ECF No. 27. In the order, I stated that, based upon the record as it currently stood, Petitioner not only could not meet the Table elements for a SIRVA injury, but would also likely be unable to

establish causation-in-fact. *Id.* 6, 6 n.4 (citing the SIRVA QAI - 42 C.F.R. § 100.3(c)(10) and the three-pronged test for causation - *Althen v. Sec'y of Health & Hum. Servs.*, 518 F.3d 1274, 1278 (Fed. Cir. 2005)). I further noted that Petitioner had provided no evidence, other than the timing of his injury, which would support the establishment of a logical cause and effect showing the Tdap vaccine was the cause of his left shoulder pain, and that there was significant evidence supporting the proposition that this pain was more likely caused by the workplace injury Petitioner suffered on March 10, 2019 – an issue which, if preponderantly supported, would defeat *any* form of the claim, Table or not. Order to Show Cause at 6.

After requesting additional time to act on several occasions (ECF Nos. 28-29), Petitioner filed a single additional item of evidence: a signed declaration³ from a coworker. Exhibit 19, filed Sept. 27, 2022, ECF No. 30. In it, the co-worker indicated that Petitioner had "told [him] the day of his accident that his shoulder was not working correctly, and that those symptoms began following his tetanus vaccination." *Id.* at ¶ 2. Noting that Petitioner previously was "in great physical shape" (*id.*), the co-worker described the physical limitations and difficulties Petitioner experienced thereafter (*id.* at ¶ 3). Petitioner provided no additional evidence or argument.

The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). According to the most recent version of the Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.

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³ Although not an affidavit, the declaration is signed under penalty of perjury as required pursuant to 28 U.S.C.A. § 1746.

SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10). If a petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen,* 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury" to establish that the vaccine was a

substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. Id.

Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

III. Relevant Factual History

Although there is an absence of prior medical records in this case,⁴ those records which have been filed reveal Petitioner worked as a bull rider when younger and sustained numerous traumatic injuries during that time. *See*, e.g., Exhibit 3 at 31. He underwent multiple prior shoulder surgeries – including on his left shoulder in 1994 and his right shoulder in 2000. *E.g.*, *id*. And Petitioner readily acknowledges his prior left shoulder condition and surgery. Petition at ¶ 3; Exhibit 5 at ¶ 4; Exhibit 18 at ¶ 5. At the time of vaccination, Petitioner had also admitted to regular marijuana use for chronic pain. *E.g.*, Exhibit 2 at 28-29.

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⁴ The only medical record from prior to vaccination is an initial visit to Dear Creek Family Healthcare and Wellness Clinic for a cold, fever, and body pain on February 21, 2019 – less than three weeks prior to vaccination. Exhibit 9 at 123-36.

On March 10, 2019, while reversing a motorized pallet jack at his place of employment (Associated Wholesale Groceries, Inc.), Petitioner sustained an injury to his left ankle after it became trapped between the machine he was operating and shelving. Exhibit 3 at 68 (initial report in emergency room); Exhibit 2 at 28 (orthopedic assessment). While at the emergency room, he was administered a Tdap vaccine in his left deltoid. Exhibit 14 at 7.

When seen at the clinic the next day – March 11, 2019 - Petitioner indicated that "[h]e went to McBride ER and states they gave him a tetanus shot in his arm and his arm hurts more than his ankle." Exhibit 3 at 59. However, the remainder of the medical record focuses on his ankle injury. Petitioner admitted to "prior fractures of the left lower leg for which he had plates and screws placed years ago due to bull riding," and indicated he used marijuana three times a day for chronic pain. *Id*.

At a follow-up visit for his left ankle contusion on March 22nd, Petitioner "also complain[ed] of some soreness in his left shoulder where he received his tetanus shot." Exhibit 3 at 52. By his next visit on March 25th, he reported that his left shoulder pain "had been getting worse," adding that "[y]esterday, he pulled about 250 cases and since then he hasn't really been able to use his arm because of the increased pain." *Id.* at 49. He indicated that his shoulder pain "started after he had his tetanus injection a couple of weeks ago and when he first injured his ankle." *Id.* The orthopedist assessed Petitioner as having "[l]eft shoulder pain with a history of a tetanus injection into the left shoulder . . . [and] a left ankle contusion," ordered testing, prescribed medication, and indicated he would consider ordering an MRI if Petitioner's symptoms persisted. *Id.* at 50.

Two days later, Petitioner reported improvement in his left shoulder movement but continued significant pain, "mostly in the lateral shoulder and kind of deep in the shoulder." Exhibit 3 at 46. The orthopedist ordered MRIs of Petitioner's left shoulder and ankle. *Id.* at 47; see *id.* at 42-45 (results of MRIs performed that same day). The shoulder MRI revealed "[l]eft shoulder degenerative changes with slight labral tearing and possible long head of the biceps tearing and rotator cuff fraying." *Id.* at 39. These findings were described as having "some degenerative association that are likely old." *Id.*

The first time Petitioner sought treatment for *only* his left shoulder pain occurred on April 5, 2019. Exhibit 3 at 35. Angry that no physician had taken his complaints regarding his left shoulder pain seriously, Petitioner reported that his symptoms began the day after vaccination, stating "that the next morning he woke up and he couldn't use his shoulder." *Id.* Similarly, the medical record from Petitioner's March 29th visit indicated his complaints of left shoulder pain began the day after his workplace injury and subsequent vaccination. *Id.* at 40. The orthopedist recommended anti-inflammatories, a steroid injection, and PT, acknowledging that the recommendation of another injection,

as opposed to surgery, might be counterintuitive but was the best course of treatment. *Id.* at 36. After some discussion, Petitioner consented to the orthopedist's plan. *Id.*

On May 20, 2019, Petitioner underwent his first independent medical examination ("IME") of both his left ankle and left shoulder conditions. Exhibit 3 at 24-28. The medical history section of this record includes Petitioner's description of left shoulder pain that woke him up the night of March 10, 2019, which he thought was due to the Tdap vaccine he received. *Id.* at 24. After examining Petitioner, the physician opined that, in addition to the left ankle injury, Petitioner "did sustain injury to his left shoulder at the time of his accident." The physician stressed that Petitioner reported "that his left shoulder and arm were jerked due to holding on to the steering wheel." *Id.* Thus, this record suggested that Petitioner's shoulder pain was a product of his accident, rather than due to the vaccine he received in the wake of the accident.

At a second IME – performed on August 26, 2019 - Petitioner again reported an injury to both his left ankle *and shoulder* when driving motorized pallet jack at work on March 10th. Exhibit 4 at 74. He stated that "he was reversing the pallet jack with his left hand on the steering wheel while looking over his left shoulder. . . , pinched his left foot between the jack and rack, and his left shoulder was 'snapped back' as the handlebar twisted." *Id.* Although the physician performing this second IME opined Petitioner's left foot and toe complaint were due to the March 10th workplace injury, he indicated Petitioner's current left shoulder complaints were not. *Id.* at 79. However, he provided no rationale for his decision, and did not discuss the etiology of Petitioner's left shoulder pain further. *Id.* at 74-80.

On December 26, 2019, the Judge in Petitioner's workers' compensation claim ordered a third IME specifically to determine whether his left shoulder injury was related to his March 10th workplace accident. Exhibit 12 at 35-37. The orthopedic surgeon who performed the IME on January 24, 2020, diagnosed Petitioner with "a left shoulder strain with intra-articular pathology consistent with a superior labral tear and anterior and anterior inferior labral tear and impingement with rotator cuff tendinitis and interstitial tearing of the long head of the biceps tendon." Exhibit 3 at 12. Noting Petitioner's "prior history of injury and surgery with early onset degenerative changes of that left shoulder," the orthopedic surgeon opined that "[b]ased on the mechanism of injury and [Petitioner's] current condition, [he] believe[d] that the injury that occurred on March 10, 2019. represents a significant and identifiable aggravation of a pre-existing condition." *Id*.

When treating Petitioner again on June 11, 2020, the orthopedic surgeon reiterated his diagnosis, which included a SLAP⁵ tear and the likelihood that Petitioner had suffered

⁵ SLAP stands for Superior Labrum Anterior Posterior. MEDICAL ABBREVIATIONS at 552 (16th ed. 2020).

a work-related left shoulder injury. Exhibit 12 at 16-17. He recommended arthroscopic surgery. *Id.* at 17.

IV. Analysis

Petitioner's injury does not meet the definition for a Table SIRVA injury, given the record evidence of a preexisting condition and potential alternative cause. There is significant, reliable evidence establishing that Petitioner had a prior history of left shoulder pain, inflammation, and dysfunction, plus a current condition which would explain his left shoulder pain. 42 C.F.R. § 100.3(c)(10)(i) & (iv) (first and fourth QAI criteria).

Additionally, Petitioner cannot provide the preponderant evidence needed to prove actual causation. Specifically, he cannot satisfy the second *Althen* prong, which requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1375-77 (Fed. Cir. 2009)); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury") (quoting *Althen*, 418 F.3d at 1280).

Although the physicians who initially treated Petitioner, from early March through April 2019, memorialized Petitioner's stated belief that his left shoulder pain was vaccine-caused, only the orthopedist (who saw Petitioner on April 5, 2019) seemed to accept that causal connection. However, it appears that he was not provided the history Petitioner *subsequently* gave of his left hand on the motorized pallet jack and a jerking of his left shoulder. When Petitioner provided this additional information, *all treating physicians* - including the two who performed the first and third IMEs - opined that Petitioner's left shoulder pain was caused by the workplace injury. The only exception is the physician who performed the second IME, who opined that Petitioner's left shoulder pain was unrelated to his March 10th workplace injury. However, this physician did not mention the Tdap vaccine Petitioner received or provide any further information as to causation. Thus, the evidence from Petitioner's treating physicians overwhelmingly favors the March 10th workplace accident as the cause of Petitioner's left shoulder pain.

The only other evidence in the medical records which would support vaccine causation are the contemporaneously-provided statements by Petitioner that he believed his injury was vaccine caused. However, these statements reflect Petitioner's initial belief,

which transformed over time, as evidenced by the totality of the medical record. See, e.g., Exhibit 2 at 17 (indicating Petitioner "is working on seeing whether his shoulder can be causally related to this accident"). Additionally, Petitioner described a pain onset of the next day or, at the earliest, that night – timing more conducive to an acute shoulder strain. And conditions such as Petitioner's SLAP tear are generally not attributable to an incorrectly administered vaccination.

Despite due opportunity, the Petitioner has identified no additional proof that would alter my earlier analysis. Following the issuance of my Order to Show Cause, Petitioner provided only the signed declaration of a co-worker. Exhibit 19. Although the co-worker provided helpful information regarding the limitations Petitioner later exhibited, he otherwise simply recounted Petitioner's belief that the vaccine was the cause of his shoulder injury. *Id.* at ¶¶ 2-3.

When providing evidence of actual causation, a petitioner is not required to eliminate all alternative causes. *Walther v. Sec'y of Health & Hum. Servs*, 485 F.3d 1146, 1149 (Fed. Cir. 2007). However, the lack of alternative cause may be included as part of evidence to satisfy the "did cause" prong. *Id.* at 1149-50 (referencing *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1359 (Fed. Cir. 2007)). If a petitioner relies upon the lack of an alternative cause, Respondent may introduce evidence of an alternative cause to rebut Petitioner's arguments. And if Petitioner can establish a *prima facia* case for causation without relying upon the lack of an alternative cause, Respondent still may counter Petitioner's claim by introducing evidence to show there is another source for Petitioner's pain. Section 13(a)(1)(B). However, he then has the burden of providing preponderant evidence to support the existence of an alternative cause. *Walther*, 485 F.3d at 1152.

Petitioner has failed to provide the evidence needed to establish a *prima facie* case for causation. He has provided no evidence, other than his personal belief and the timing of his injury, which would support the establishment of a logical cause and effect showing the Tdap vaccine was the cause of his left shoulder pain. And there is significant evidence supporting the proposition that this pain was caused by the workplace injury Petitioner suffered on March 10, 2019. For these reasons, the entirety of the claim warrants dismissal – for it is evident that even a non-Table, causation-in-fact version of the claim cannot succeed.

Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support his allegation of a left shoulder injury which meets the Table SIRVA definition. Nor can he preponderantly establish that his injury was more

likely than not caused by the Tdap vaccine he received on March 10, 2019. Petitioner was informed that failure to provide preponderant to support his claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for the claim.

Accordingly, this case is DISMISSED for failure to prosecute and insufficient evidence. The Clerk of Court shall enter judgment accordingly.⁶

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master

⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.